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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,457

02/10/2004

Eitan Konstantino

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/776,457

Applicant(s)

KONSTANTINO ET AL.

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-15 and 17-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 7-15, 17-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This action is in response to the Request for Continued Examination filed on 5/18/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Pallazza (US 2003/0083687).

Pallazza discloses a catheter (Item 108) and a radially expansible balloon having a permanent fold line extending helically around the balloon (Fig 11B). Furthermore, the number of fold lines and their relative location is shown in Fig 11B. The groove and crease are considered to be substantially equivalent to the pleat described in Paragraph 91.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Tsukashima et al. (US 5,350,361)

Should Applicant argue that the fold lines of Pallazza are not permanent or formed prior to folding, the Examiner is providing a rejection on the grounds of obviousness. Tsukashima teaches that permanent fold lines allow the balloon to collapse upon deflation into the desired, predetermined shape (Col 3 Lines 25-45). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's folds to include Tsukashima's permanent lines. Such a modification would cause the balloon to symmetrically deflate.

Furthermore, the flaps and lobes of claims 7 and 8 are described in both Pallazza (Paragraph 2) and Tsukashima (Col 2 Line 5) in order to minimize the profile of the balloon.

Claims 9-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Shiber (U.S. 2002/0151924).

Pallazz discloses the invention substantially as claimed as stated above. Pallazza does not disclose a scoring structure. Shiber teaches a scoring structure (Item 92) to engage an obstruction in a vessel. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's balloon to include Shiber's scoring element. Such a modification would provide a means to engage an obstruction in a vessel. Furthermore, aligning the

scoring element with the helical fold line would be obvious in order to shield the scoring elements until inflation.

Regarding independent claim 15, Pallazza discloses the structure of the balloon including the groove and recess. The recess is formed when the balloon is folded with the wings, flaps, or lobes as stated in the reference. The scoring element of Shiber would be placed in this recess. The Shiber reference discloses the scoring element placed in a recess (Fig 7) so it would be obvious to place the element in the helical recess of Pallazza.

The limitations of the other dependent claims are found in Fig 7 and Paragraph 39.

Claims 9-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Tsukashima et al. (US 5,350,361) further in view of Shiber (U.S. 2002/0151924).

This rejection is provided should the Applicant argue the Pallazza reference lacks permanent fold lines. Pallazza and Tsukashima disclose the invention substantially as claimed as stated above. They do not disclose a scoring structure. Shiber teaches a scoring structure (Item 92) to engage an obstruction in a vessel. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza and Tsukashima's balloon to include Shiber's scoring element. Such a modification would provide a means to engage an obstruction in a

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vessel. Furthermore, aligning the scoring element with the helical fold line would be obvious in order to shield the scoring elements until inflation.

Regarding independent claim 15, Pallazza and Tsukashima disclose the structure of the balloon including the groove and recess. The recess is formed when the balloon is folded with the wings, flaps, or lobes as stated in the references. The scoring element of Shiber would be placed in this recess. The Shiber reference discloses the scoring element placed in a recess (Fig 7) so it would be obvious to place the element in the helical recess of Pallazza.

Claims 1-4, 7-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barath (US 5,616,149) in view of Pallazza (US 2003/0083687).

Barath discloses a catheter body (1), a balloon (2), the balloon having a permanent fold line wherein the fold line is a groove (19), and a scoring structure (Figure 15 Item 22). Barath does not disclose the balloon fold line being helical. Pallazza teaches helical fold lines (Figure 11B). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Barath's balloon to include helical fold lines. Helical folds in balloons provide the advantage of a reduced diameter upon entry into the vessel.

Claims 9-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Barath (US 5,616,149).

Pallazza discloses the invention substantially as claimed as stated above.

Pallazza does not explicitly disclose a scoring structure, the scoring element attached to the catheter body and not to the outer surface of the balloon. Barath teaches a scoring structure (6) in grooves (19) of a balloon wherein the scoring element is attached to the catheter (Figure 15 Item 20) but not the balloon. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's balloon to include Barath's scoring structure. Such a modification would provide a means for cutting into a vessel wall for recanalization of the vessel.

Response to Arguments

Applicant's arguments filed 4/04/2007 have been fully considered but they are not persuasive.

The Applicant has amended the claims to include a process to form the fold line on the balloon. The Examiner does not consider this additional limitation to have any patentable weight. The process does not materially change the structure. Therefore, the references are considered to read on the claim. The Examiner also notes that general scoring of a surface to form a line is considered within the purview of one having ordinary skill in the art. The Barath reference clearly discloses a structure similar to that claimed. The only difference is that of helical fold lines. This feature is well known in the art for reducing the deflated diameter of the balloon. The Pallazza reference shows such a feature, but it is noted that there are many references, several of which have been presented during the prosecution of this case, which also teach

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helical fold lines on a balloon. This response is considered to address the Applicant's arguments.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/22/07